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7590 05/09/2007 Steven J. Shumaker SHUMAKER & SLEFFERT, P.A.		EXAMINER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)		
Office Action Summary		10/723,316	SPINELLI ET AL.		
		Examiner	Art Unit		
		George Manuel	3762		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
2a)☐ 3)☐	Responsive to communication(s) filed on <u>08 Ja</u> This action is FINAL . 2b)⊠ This Since this application is in condition for allowan closed in accordance with the practice under <i>E</i>	action is non-final. nce except for formal matters, pro	•		
Dispositi	on of Claims				
5)⊠ 6)⊠ 7)⊠	Claim(s) <u>1,3-5,7-11,14,20-30 and 33-39</u> is/are plant of the above claim(s) is/are withdraw Claim(s) <u>36-38</u> is/are allowed. Claim(s) <u>1,3-5,7-11,14,20-30 and 39</u> is/are rejection(s) <u>33-35</u> is/are objected to. Claim(s) are subject to restriction and/or	vn from consideration.			
Application	on Papers	• •			
10)	The specification is objected to by the Examine The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Conference of Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Example of the conference of the co	epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).		
Priority u	nder 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
	e of References Cited (PTO-892)	4) Interview Summary			
3) 🔯 Inform	e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date <u>8/10/06, 1/8/07</u> .	Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:			

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 3, 4, 5, 7-11, 14, 20-27 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27, 36-37 of copending Application No. 10/236,578. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is merely broader than the '578 application (that is, the present application allows for such stimulation to treat more conditions). The more specific claims of the '578 application anticipate the broader claims of the present application, and thus the

two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 32, and 38 of copending Application No. 10/723,903. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the sacral nerves in addition to stimulating the pudendal nerve, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 32, and 38 of copending Application No. 10/745,757. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having

ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the left and right pudendal nerves, since stimulation of various pelvic floor nerves for treating various pelvic floor disorders is well known in the art (for example, see U.s. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,355. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the sacral nerves as an alternative or in addition to stimulating the pudendal nerve, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,840. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the sacral nerves as an alternative or in addition to stimulating the various claimed nerve locations, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending

Application No. 10/836,924. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the sacral nerves as an alternative or in addition to stimulating the various claimed nerve locations, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639)

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which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/836,927. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the sacral nerves as an alternative or in addition to stimulating the various claimed nerve locations, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,970. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the

art at the time of applicant's invention to modify the claimed method to stimulate the pudendal nerve as an alternative or in addition to stimulating the various claimed nerve locations, since stimulation of pudendal nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/837,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '181 application is merely broader than the present application (that, the '181 patent allows for stimulation at more locations than the present application). The more specific claim of the present application anticipates the broader claim of the '181 application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 12. Claims 1, 3, 4, 5, 7-9, 11, 14, 20, 23 and 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2005/0209652 ("Whitehurst et al.").

Whitehurst et al. discloses a method and system for treatment of sexual dysfunction via application of a stimulating drug alone or in combination with electrical stimulation (see paragraph 0016). The system includes one or more control units (SCUs) that apply the electrical stimulation and/or one or more stimulating drugs to predetermined stimulation sites (see paragraph 0017). Electrodes are surgically implanted from an implantable pulse generator and one or more infusion outlets and/or catheters are surgically implanted to infuse drugs from an implantable pump (see paragraph 0017). The electrodes may be located at the distal portion of flexible leads (see Fig. 5 and associated text at paragraphs 0055 - 0061). Whitehurst et al. discloses that the electrodes and/or infusion outlets may be implanted adjacent any structure of

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the penis, including the prostatic plexus, the pudendal nerves, and the urethra (see paragraph 0100).

With respect to claim 3, Whitehurst et al. discloses that the leads preferably contain an array of collinear electrodes (see paragraph 0061). Examiner considers this description to anticipate "multiple electrodes disposed in an areal pattern on a planar or curved surface."

With respect to claims 4-5, Whitehurst et al. discloses that the leads and/or catheters may have a barb as a fixation mechanism (see paragraph 0098).

With respect to claims 7-8, Whitehurst et al. discloses a second lead attached to SCU 160 (see Fig. 5 and paragraph 0060).

With respect to claim 9, Whitehurst et al. discloses that parameters such as high frequency stimulation may be chosen to have an inhibitory effect (see paragraph 0064).

With respect to claim 11, Whitehurst et al. discloses that the leads (70) are preferably less than 5 mm in diameter, and more preferably less than 1.5 mm in diameter (see paragraph 0061).

With respect to claim 14, Whitehurst et al. discloses that the length of the leads is not typically longer than about 150 mm (see paragraph 0055). If such leads contain 4 collinear electrodes as preferred (see 0060-0061), such inter-electrode distance and electrode surface area are necessarily within the claimed ranges of claims 10 and 11.

With respect to claim 20, Whitehurst et al. discloses that electrical stimulation parameters may be chosen in various frequencies (see paragraph 0064).

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With respect to claim 23, Whitehurst et al. discloses the stimulation parameters (such as pulse width, infusion rate, etc) may be infused by various rates of infusion (see paragraph 0046). Examiner considers "generates electrical pulses having varying spatial or temporal phases" to encompass such generating stimulation pulses of various rates of infusion, because the timing/temporal phase of the applied stimulation is varied. Further, Whitehurst et al. discloses that multiple channels and/or multiple patterns of electrical and/or drug stimulation may be programmed by the clinician and controlled by the user in order to deal with complex dysfunctions (see paragraph 0092).

With respect to claim 26, Whitehurst et al. discloses concomitantly delivering electrical stimulation and drug infusion (see paragraph 0063).

13. Claims 1, 7-8, 14 and 20-29 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,454,840 ("Krakovsky et al.").

Krakovsky et al. discloses an implanted device called a potency package that includes a battery 40, a programmable signal circuit 42, and a pulse generator 46 (see col. 3, lines 25-35). The potency package delivers electrical stimulation pulses (see col. 3, lines 35-45) in order to provide the patient with at least partial relief from erectile/sexual dysfunction. Further, Krakovsky et al. discloses the teachings of the invention may be used for urine incontinence correction during sexual intercourse (see col. 6, lines 40-46). The device includes a medical lead having an electrode, which connects with the pelvic splanchnic nerves (see col. 3, lines 49-55). In addition, a second electrode (49) extends from the device to the pudendal nerves (see col. 4, lines 5-19). Examiner considers the broadest reasonable interpretation of the term "adjacent"

to be close, but not necessarily touching. Therefore, Examiner considers implantation of a medical lead adjacent to the pelvic splanchnic nerves and/or the pudendal nerves to necessarily result in a lead implanted "adjacent" to other nerves, such as the greater sciatic foramen, the lesser sciatic foramen, the ischial tuberosity, the sacro-tuberous ligament, the inferior rectal nerve, the perineal nerves, the scrotal nerves, Alcock's canal, and the penile dorsal nerve. As illustrated by Applicant's own Figures 3, 4B, 5, and 6, such nerve structures are close together but not necessarily touching.

For further description of application of Krakovsky et al. to claims 1, 2, 7-8, 14-29, and 32, please see the comments made in the office action dated 4/7/06.

Claim Rejections - 35 USC § 102/103

- 14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 15. Claims 1, 9, 14, 24, and 30 stand rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative as being unpatentable over, "Neural Stimulation as a method of controlling prostatitis symptoms" (Chalfin), disclosed in 1999 Selected Abstracts from the American Urological Association annual meeting.

Chalfin discloses the use of sacral nerve stimulation for treatment of chronic prostatitis. The abstract provided from the 1999 the American Urological Association

annual meeting discloses the method of claim 1, in that an implanted pulse generator and a medical lead are provided and implanted into the patient. Chaffin discloses that the medical lead is implanted adjacent to sensory nerves that supply the bladder, rectum, and pelvic floor. Chaffin discloses the sacral nerve as one stimulation site (i.e., see title and first paragraph), but does not explicitly disclose that these relevant sensory nerves may include, for example, a pudendal nerve or a sacral splanchnic nerve. Examiner considers the broadest reasonable interpretation of the term "adjacent" to be close, but not necessarily touching. Therefore, Examiner considers implantation of a medical lead adjacent to the sacral nerve to necessarily result in a lead implanted "adjacent" to other nerves, such as the pudendal nerve and the sacral splanchnic nerve because such nerve structures are close together but not necessarily touching.

In the alternative, Examiner notes that Chaflin discloses that the therapy works by applying chronic electrical stimulation to sensory nerves that supply the bladder, rectum, and pelvis floor (emphasis added). It is apparent from this teaching the Chaflin contemplates stimulation of other nerves besides the sacral nerve. Various locations of claims 1 and 30, including the pudendal nerve and sacral splanchnic nerve, are all nerves that supply the bladder, rectum and pelvis floor. It is known in the art to apply direct stimulation to these nerves in order to bypass the potential stimulation of unrelated nerve groups at the sacral roots (for example, see U.S. Patent No. 6,735,474 to Loeb et al. which teaches stimulation of pelvic floor nerves such as the pudendal nerve to treat chronic pelvic pain; col. 6, lines 17-24). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the

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implanted medical lead of Chaflin to stimulate these other sensory nerves in order to more locally stimulate the nerve that is causing the patient pain (as taught by, for example, U.S. Patent No. 6,735,474 to Loeb et al.).

Claim Rejections - 35 USC § 103

16. Claims 10, 21-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2005/0209652 ("Whitehurst et al.").

As described above, Whitehurst et al. discloses a method and system for treatment of sexual dysfunction via application of a stimulating drug alone or in combination with electrical stimulation (see paragraph 0016).

With respect to claim 10, Whitehurst et al. does not explicitly disclose that a lead extension may be utilized. The common knowledge or well-known in the art statement made by the Examiner in the Office Action mailed 4/7/06 (that lead extensions are well known in the art; see page 18 of Office Action mailed 4/7/06) is taken to be admitted prior art because applicant failed to traverse the examiner's assertion of Official Notice (MPEP2144.03(C)). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Whitehurst et al. to utilize a lead extension in order to modify the length of a lead to a desired length for implantation.

With respect to claims 21-22 and 24, Whitehurst et al. discloses that the SCU 160 allows for the electrical and/or drug stimulation parameters to be adjusted as needed for safe and efficacious treatment (see paragraph 0063), but fails to specifically

disclose the capabilities of IPG. Such IPG capabilities are well known in the art, and it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Whitehurst et al. such that the IPG is capable of generating a wide range of stimulation parameters in order to effectively treat each individual's type and degree of sexual dysfunction.

17. Claims 4, 5, 7-8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Neural Stimulation as a method of controlling prostatitis symptoms" (Chalfin) in view of U.S. Patent No. 6,055,456 ("Gerber").

As discussed above, Chalfin teaches implanted stimulation systems for stimulating portions of the sacral nerves for treatment of various ailments, such as prostatitis, chronic pelvic pain, or urinary incontinence disorders. Gerber teaches a prior art implantable medical lead for stimulation of the sacral nerves that simplifies the implant procedure (i.e., see col. 2, lines 30-40). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Chalfin to utilize the medical lead as taught by Gerber in order to simplify the implant procedure while still providing adequate electrical stimulation to the sacral nerve.

With respect to claims 4 and 5, Gerber teaches the lead has an active fixation device (see anchoring mechanism 50 and associated text).

With respect to claims 7-8, Gerber teaches that implanting two medical leads for delivering electrical stimuli is known in the art (see col. 1, lines 35-55). It would have

been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Chalfin to utilize the multiple leads in a stimulation system as taught by Gerber in order to stimulate multiple target areas simultaneously or sequentially.

With respect to claim 10, Gerber does not explicitly disclose that a lead extension may be utilized. The common knowledge or well-known in the art statement made by the Examiner in the Office Action mailed 4/7/06 (that lead extensions are well known in the art; see page 18 of Office Action mailed 4/7/06) is taken to be admitted prior art because applicant failed to traverse the examiner's assertion of Official Notice (MPEP2144.03(C)). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Chalfin to utilize a lead extension in order to modify the length of a lead to a desired length for implantation.

With respect to claim 11, Gerber teaches a lead body having a diameter of .050 inches (or 1.27 mm), the lead body being made of polyurethane or silicone (col. 4, lines 5-12).

Allowable Subject Matter

Claims 33-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 36-38 are allowed.

Response to Arguments

Applicant's arguments filed 1/8/07 have been fully considered but they are not persuasive.

Features in the claims are not ignored by interpreting the language of "adjacent" in its broadest reasonable meaning.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is 571-272-4952. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George Manuel Primary Examiner